U.S. DEPARTMENT OF AGRICULTURE SECRETARY OF AGRICULTURE

In re:)	FMIA Docket No. 07-0191
	Stagno's Meat Company, Brian R. Stagno And Richard A. Stagno,)	
	Respondents)	CONSENT DECISION

This proceeding was instituted under the Federal Meat Inspection Act (FMIA), as amended (21 U.S.C. §§ 601 *et seq.*), to withdraw federal inspection services from respondents. This proceeding was commenced by a complaint filed by the Administrator, Food Safety and Inspection Service (FSIS), United States Department of Agriculture (USDA). This decision is entered pursuant to the consent decision provisions of the rules of practice applicable to this proceeding (7 C.F.R. § 1.138).

The respondents admit the findings of fact, as set forth herein, and specifically admit that the Secretary has jurisdiction in this matter. The respondents neither admit nor deny the remaining allegations and waive oral hearing and further procedure. Respondents and the owners, officers, directors, partners, successors, assigns, and affiliates of respondent Stagno's Meat Company waive any claim against complainant under the Equal Access to Justice Act of 1980 (5 U.S.C. § 504 *et seq.*) and waive any other action against USDA or its employees in connection with this proceeding and the facts and events that gave rise to this proceeding. Respondents consent and agree, for the purpose of settling this proceeding and for such purpose only, to the entry of this decision.

The complainant agrees to the entry of this decision.

FINDINGS OF FACT

- 1. Respondent Stagno's Meat Company ("Stagno's") is, and at all times material herein was, a corporation organized and existing under the laws of California, operating a meat slaughter and processing plant at 725 Zeff Road, Modesto, California 95351.
- 2. Respondent Brian R. Stagno, who resides at 513 California Street, Escalon, California 95320 is, and at all times material herein was, the manager of Stagno's Meat Company.
- 3. Respondent Richard A. Stagno, who resides at 17751 Steinegul Road, Escalon, California 95320 is, and at all times material herein was, the president of Stagno's Meat Company.
- 4. On March 27, 2000, respondents were granted federal inspection services pursuant to the FMIA at the above-named establishment, designated by Official Establishment Number 02875 M.
- 5. On May 25, 2007, FSIS issued a Notice of Suspension letter to respondents and suspended inspection services alleging failure to effectively implement and maintain the required Sanitation Standard Operating Procedures (SSOPs) and Hazard Analysis Critical Control Points (HACCP) plans in accordance with 9 C.F.R. Parts 416 and 417; failure to maintain control of specified risk materials (SRMs) in accordance with 9 C.F.R. § 310.22; and failure to comply with humane slaughter and handling regulations.
- 6. On June 5, 2007, this suspension was held in abeyance pending verification of corrective actions and preventive measures with respect to the conditions of the facility.

- 7. On August 21, 2007, FSIS issued a Notice of Reinstatement of Suspension letter to Respondents alleging:
- (a) failure to remove, segregate and dispose of SRMs in accordance with 9 C.F.R. § 310.22 to prevent the use of these materials for human food;
 - (b) failure to maintain SSOPs in accordance with 9 C.F.R. Part 416; and
 - (c) failure to maintain HACCP plans in accordance with 9 C.F.R. Part 417

CONCLUSIONS

The respondents having admitted the jurisdictional facts and the parties having agreed to the entry of this decision, this decision will be entered.

ORDER

- 1. Federal meat inspection services under the FMIA are withdrawn from respondents and respondent Stagno's owners, officers, directors, successors and assigns for a period of three (3) years beginning on the effective date of this Order. Provided, however, the withdrawal of inspection shall be held in abeyance, and inspection services shall be provided to respondents for so long as the conditions set forth below, in addition to all other applicable requirements for inspection services, are met.
- 2. Prior to the resumption of inspection services, and subject to verification by FSIS, respondents shall demonstrate compliance with FSIS statutory and regulatory requirements, including, but not limited to, 9 C.F.R. Parts 310, 416 and 417, and upon a review and examination of (a) respondents' SSOP, HACCP, Specified Risk Material, residue, Escherichia coli, and other written sanitation, process controls, corrective actions, and employee training and

sampling and testing programs and (b) of the physical and sanitary conditions of the establishment.

Sanitation Performance Standards

- 3. Prior to the resumption of inspection services, and subject to verification by the FSIS District Manager and/or designees, respondents shall:
- (a) develop written procedures, including monitoring, corrective action, and recordkeeping procedures that the establishment will implement to operate and maintain respondent Stagno's establishment, including its premises, facilities, equipment and outside premises, in a manner sufficient to prevent the creation of insanitary conditions and practices, comply with the requirements of the Sanitation Performance Standard (SPS) regulations (9 C.F.R Parts 416.1 to 416.6), and ensure that meat and meat products prepared, stored and packed are not adulterated; and
- (b) address and repair any premises, facility and/or equipment issues, identified by FSIS at the time of the physical plant review conducted pursuant to paragraph 2 of this Order, that do not comply with FSIS regulatory requirements.
- 4. Upon the resumption of inspection services, and subject to verification by the FSIS District Manager and/or designees, respondents shall:
- (a) operate and maintain, at all times, respondent Stagno's establishment, including its premises, facilities, equipment and outside premises, in a manner sufficient to prevent the creation of unsanitary conditions and practices, comply with the requirements of the SPS regulations, and ensure that meat and meat food products are not adulterated; and

(b) routinely assess its written SPS procedures to evaluate their effectiveness, and make necessary improvements, corrective actions, or repairs to the program or to the establishment premises, facility or equipment needed to ensure and maintain sanitary conditions.

Sanitation Standard Operating Procedures

- 5. Prior to the resumption of inspection services, and subject to verification by the FSIS District Manager and/or designees, respondents shall:
- (a) develop written sanitation standard operating procedures (SSOP) to describe the monitoring activities, recordkeeping, and other procedures respondents will conduct, implement and maintain, on a daily and ongoing basis, before, during, and after operations, in accordance with this Order and regulatory requirements, 9 C.F.R. Parts 416.11 to 416.16, to ensure sanitary conditions and prevent product adulteration; and
- (b) address specific procedures within the written SSOP, including the following: (i) cleaning and sanitizing equipment and utensils; (ii) written instructions for complex equipment use and methods of cleaning; (iii) proper handling, storage, denaturing, and disposal of inedible products; (iv) re-conditioning of contaminated product; and (v) employee hygienic practices.
- 6. Upon the resumption of inspection services, and subject to verification by the FSIS District Manager and/or designees, respondents shall:
- (a) implement and maintain, on a daily and ongoing basis, the SSOP system as provided in paragraph 5 of this Order and regulatory requirements of 9 C.F.R. Part 416 to ensure sanitary conditions and prevent product adulteration; and
- (b) implement corrective and preventative actions as required by 9 C.F.R. § 416.15 and routinely evaluate the effectiveness of its SSOP and implement necessary modifications as

required by 9 C.F.R. § 416.14 to ensure that regulatory requirements for the maintenance of sanitary conditions and the production and distribution of safe, wholesome, not adulterated and properly labeled products in commerce are met.

Hazard Analysis and Critical Control Points (HACCP) System

- 7. Prior to the resumption of inspection services, and subject to verification by FSIS, respondents shall:
- (a) develop HACCP Plans to control and prevent the introduction of food safety hazards in meat and meat food products; and
- (b) describe the process controls and procedures respondents will conduct, implement and maintain on a daily and on-going basis, including, but not limited to the following: (i) address biological, chemical, and physical food safety hazards reasonably likely to occur at each process step in the slaughter process; (ii) identify *Escherichia coli* 0157:H7 as a food safety hazard that is reasonably likely to occur in the slaughter and Raw Not Ground process; (iii) ensure each critical control point in the slaughter process has measures to prevent, eliminate, or reduce to an acceptable level, biological, chemical or physical hazards; (iv) address the process steps in the hazard analysis to include preventive measures or controls, where employee hygiene/practices, faulty equipment, and sanitary dressing procedures have created unsanitary conditions or product contamination at those process steps; (v) assess the multiple interventions in the slaughter process that are used to control food safety hazards and determine their capabilities to ensure that pathogens of concern are actually being prevented, eliminated or reduced to an acceptable level, and validate the food safety system in accordance with 9 C.F.R. Part 417.4(a); and (vi) provide supporting and decision making documentation for the hazard

analysis and HACCP plan, and validation protocols, including all parameters used in the validation protocols, and data to support the food safety system.

- 8. Upon the resumption of inspection services, and subject to verification by the FSIS District Manager and/or designees, respondents shall:
- (a) implement, validate and maintain, on a daily and on-going basis, the HACCP systems and plans in accordance with the regulatory requirements, 9 C.F.R. Part 417;
- (b) implement timely and appropriate corrective and preventive actions, as required by 9 C.F.R. § 417.3, and reassess and modify its HACCP system and plans, as necessary to ensure that the regulatory requirements for the control and prevention of pathogens, and the production and distribution of wholesome, not adulterated and properly labeled products are met, as required by 9 C.F.R. Part 417; and
- (c) assess, validate and test the adequacy of the critical control points, critical limits, monitoring and record-keeping procedures, and corrective actions set forth in the HACCP system and plans to ensure that the establishment's food safety systems remain validated over time, as required by 9 C.F.R. Part 417.

Humane Methods of Slaughter Program

- 9. Prior to the resumption of inspection services, and subject to verification by the FSIS District Manager and/or designees, respondents shall develop a written humane method of slaughter program to:
- (a) ensure any livestock slaughtered or handled in connection with slaughter at respondents' establishment comply with the Humane Methods of Slaughter Act and 9 C.F.R. Part 313; and

- (b) ensure livestock are placed in holding pens that provide functioning watering systems;
 - (c) ensure all animals that are held overnight are provided appropriate feed stuff;
- (d) include monitoring, verification corrective and preventive actions, and recordkeeping that it will implement and maintain on a daily and on-going basis, to ensure that livestock are treated in a humane manner prior to slaughter; and
- (e) include procedures for humane handling, stun gun maintenance, insensibility of stunned animals, stunning of animals, prods and driving tools.
- 10. Upon the resumption of inspection services, and subject to verification by the FSIS District Manager and/or designees, respondents shall implement and maintain, on a daily basis, the humane method of slaughter program, as provided in paragraph 9.

Specified Risk Material Program

- 11. Prior to the resumption of inspection services, and subject to verification by the FSIS District Manager and/or designees, respondents shall:
- (a) develop a written hazard control program for specified risk material (SRM), including monitoring, verification, corrective and preventive actions, and recordkeeping that respondents will implement and maintain, on a daily and on-going basis, to ensure the control of SRM material and regulatory compliance with 9 C.F.R. Parts 309, 310, 311 and 314; and
- (b) address specific procedures within its SRM program, including the following: (i) identification of animals; (ii) determination of the age of cattle; (iii) receiving and holding controls; (iv) removal, segregation and control of SRM material from cattle slaughtered at the

establishment; (v) prevention of cross-contamination with edible products; and (vi) monitoring, verification, corrective and preventive actions and recordkeeping procedures.

12. Upon the resumption of inspection services, and subject to verification by the FSIS District Manager and/or designees, respondents shall implement and maintain, on a daily and on-going basis, the written SRM removal program, as provided in paragraph 11.

Escherichia coli Sampling and Testing Program

- 13. Prior to the resumption of inspection services, and subject to verification by the FSIS District Manager and/or designees, respondents shall develop, implement, and maintain a Escherichia coli Biotype I (E. coli) sampling and testing program and describe the procedures, sampling methodology, frequency, analysis and recordkeeping that respondents will conduct and maintain to comply with 9 C.F.R. § 310.25.
- 14. Upon the resumption of inspection services, and subject to verification by the FSIS District Manager and/or designees, respondents shall:
- (a) implement and maintain, the E. coli Biotype I sampling and testing program, as provided in paragraph 13;
- (b) collect samples and test for E. coli Biotype I in accordance with 9 C.F.R. Part 310.25 and record and analyze sample results; and
 - (c) collect samples and test E. coli O157:H7 and record and analyze sample results.

Residue Control Program

15. Prior to the resumption of inspection services, and subject to verification by the FSIS District Manager and/or designees, respondents shall:

- (a) develop a written residue control program, including monitoring, verification, corrective and preventive actions, and recordkeeping to ensure that livestock suspected of having been treated with or exposed to any substance that may impart a residue are not slaughtered or processed for intended human consumption in accordance with the requirements of 9 C.F.R. Part 309.16; and
- (b) address specific procedures within respondents' residue control program, including the following: (i) receiving of animals; (ii) identification with lot number of animals for trace back to suppliers; (iii) documenting and recordkeeping of findings; (iv) notification of violations to suppliers; and (v) implementation of corrective actions and preventive measures.
- 16. Upon the resumption of inspection services, and subject to verification by the FSIS District Manager and/or designees, respondents shall implement and maintain, on a daily and on-going basis, the written residue control program, as provided in paragraph 15.

Non-Intimidation and Interference Policy

- 17. Prior to the resumption of inspection services, and subject to verification by the FSIS District Manager and/or designees, respondents shall:
- (a) develop a written company policy and action plan to address measures that will be taken by plant management, before the resumption of inspection services and on a daily and ongoing basis, to ensure that respondents, and respondent Stagno's officers, employees, or agents do not intimidate, interfere with, assault, impede, or threaten FSIS personnel; and
- (b) include in the policy and action plan: (i) a statement of respondent's commitment to ensure the safety and non interference with FSIS personnel; (ii) written guidelines prohibiting assaults, threats of assault, intimidation or interference with FSIS personnel; (iii) preventive

measures and assurances to be taken by plant management to preclude any acts of intimidation, assault, or interference of FSIS personnel; (iv) corrective actions to be implemented by plant management if instances are reported; (v) disciplinary actions and sanctions against individuals involved in reported incidents; and, (vi) training for all current and future managers and employees in the company policy and action plan.

- 18. Upon resumption of inspection services, and subject to verification by the FSIS District Manager and/or designees, respondents shall:
 - (a) implement the company policy and action plan, as provided in paragraph 17;
- (b) ensure that the company policy is permanently displayed in a prominent location; and
- (c) require strict adherence to the company policy on the part of all current and future managers and employees and take and document corrective action, including disciplinary action, when necessary.
- 19. Within 120 calendar days of resumption of inspection services, respondents and its employees and management personnel shall participate in a Mediation Session with FSIS inspection officials. Said mediation session shall be arranged by the FSIS District Manager and/or designees and shall emphasize FSIS laws, maintaining professionalism and safety and precluding any acts of workplace violence in the establishment's working environment. FSIS will select the date, location and set the agenda for said session.

Establishment Management and Employee Training

20. Prior to the resumption of inspection services, and subject to verification by the FSIS District Manager and/or designees, respondents shall:

- (a) designate in writing, one full-time person and one alternate person who shall be responsible for the implementation, coordination, monitoring, recordkeeping, review and maintenance of the facility's food safety and sanitation programs and the requirements of this Order;
- (b) develop a training program for all current employees and management personnel and future hires to ensure that employees are trained in all aspects of food safety measures and regulatory requirements, including the requirements of the SPS, SSOP, HACCP, residue control, removal and control of SRM's, *E. coli* sampling and testing, recordkeeping procedures, and good manufacturing procedures relevant to each employee's position;
- (c) train all current employees and management personnel in all aspects of food safety measures and regulatory requirements of SPS, SSOP, HACCP, residue control, SRM's removal and control, *E. coli* sampling and testing, recordkeeping procedures and the terms and conditions of this Order; and
- (d) provide the Director, Evaluation and Enforcement Division (EED) with documentation: (i) listing the names of management personnel and employees that will be trained prior to the resumption of inspection services; (ii) naming the individual and alternate responsible for the employee training; and (iii) showing that the trainers have completed a course of instruction in HACCP that complies with 9 C.F.R. Part 417.7.
- 21. Respondents shall train and educate any new employee(s) and management personnel, consistent with the requirements of this Order, within thirty (30) days of employment.
- 22. Respondents shall conduct annual training for all employees, management personnel current and new, consistent with the requirements of this Order.

Establishment Management and Personnel

- 23. Prior to the resumption of inspection services, and subject to verification by the FSIS District Manager and/or designees, respondents shall modify the responsibilities of establishment personnel as follows:
- (a) Mr. Richard Stagno may retain his position as President of respondents' corporation, except that his responsibilities as President shall not interfere with or circumvent the assigned responsibilities and authorities of the In-plant and HACCP Manager as outlined in paragraph (c). As President, he will be responsible for overall operations with emphasis on sales and buying of livestock and may not: (i) exercise operational, supervisory or managerial controls over any matters regulated by the FMIA and PPIA or (ii) interact with FSIS personnel.
- (b) Mr. Brian Stagno may retain his position as Vice-President of respondents' corporation, except that his responsibilities as Vice-President shall not interfere with or circumvent the assigned responsibilities and authorities of the In- plant and HACCP Manager. As Vice-President, he will be responsible for hiring and firing of personnel, financial recordkeeping, production operations, sales and marketing of finished products and may not: (i) exercise operational, supervisory or managerial controls over any matters regulated by the FMIA or PPIA; or (ii) interact with FSIS personnel.
- (c) Mr. Wesley Jones will assume the position of In-plant and HACCP Manager for respondents' corporation. As In- plant and HACCP Manager, he will be responsible for: (i) overall management and implementation, coordination, monitoring, verification, validation, reassessment, pre-shipment review, record keeping, review and maintenance of the establishment's sanitation, SSOP, HACCP, *E. coli*, residue, SRM, and other sanitation, process control, sampling and testing programs, systems, and plans, as required by and consistent with

the FMIA, the meat inspection regulations, and the requirements of this Order; (ii) communicate directly with FSIS personnel at all levels; (iii) make oral and written responses to noncompliance records and appeal the findings of FSIS program personnel; (iv) slow, hold-up or stop production; (v) remove product from production; (vi) take positive control of any manufactured or stored product which is believed to be adulterated, misbranded or otherwise unsafe; (vii) make decisions concerning product disposition, including product destruction; (viii) recall any potentially adulterated or misbranded product.

- 24. Prior to the resumption of inspection services, and subject to verification by FSIS, Respondents shall submit all documentation, including job descriptions for Richard Stagno, Brian Stagno and Wesley Jones covering the duties and responsibilities of their positions as limited by paragraph 23 for concurrence by the Director, EED.
- 25. Within thirty (30) days of the resumption of operations, and subject to the concurrence of the Director, EED, respondents shall designate, in writing, an alternate responsible for conducting the functions and duties of the In-plant and HACCP Manager in the In-plant and HACCP Manager's absence. Richard Stagno and Brian Stagno may not serve as alternates for the In-Plant and HACCP Manager.
- 26. Prior to the resumption of inspection services, respondents shall take all actions necessary to ensure that the In- plant and HACCP Manager has: (i) completed a course of instruction and received certification in HACCP consistent with 9 C.F.R. § 417.7; (ii) has completed training in regulatory requirements regarding SPS, SSOP, SRM, and *E. coli* sampling and testing procedures; and, (iii) provide documentation regarding compliance with this paragraph to the Director, EED.

27. Respondents may name a new President, Vice-President, In-Plant and HACCP Manager or their alternates only upon written request to, and subject to the written concurrence of, the Director, EED.

Third Party Audits

- 28. Respondents shall, upon resumption of inspection services, cause to be made, by a qualified, independent third-party, written audits of (a) respondents' implementation, monitoring, and maintenance of its sanitation, SSOP, HACCP, SRM's and other process control, sampling and testing, and other programs; (b) the effectiveness of respondents' sanitation, SSOP, HACCP, SRM's and other process control, sampling and testing, and other programs to ensure food safety; (c) compliance with FSIS statutory and regulatory requirements; and, (d) compliance with the terms of this Order.
 - 29. The audits shall be conducted, at least as frequently, as follows:
- (a) the first audit shall be conducted within sixty (60) calendar days from the effective date of this Order; (b) subsequent audits shall be conducted every (120) calendar days thereafter for the duration of this Order.
- 30. The written audits shall include a report of findings and recommendations, if any, of the independent third-party.
- 31. Respondents shall prepare, for each audit conducted, a written response to the third-party's findings and recommendations. Respondents' written response shall identify: (a) any modifications to its SSOP, HACCP or other programs or plans; (b) any corrective actions implemented; (c) any other actions implemented or planned in response; and (d) information supporting any decision by respondents not to implement any audit recommendation.

- 32. Respondents shall make a copy of each third-party audit, a copy of respondents' written response, and copies of any notes, interviews or other documents relative to the audit available to FSIS for review and/or copying within (20) days after each audit is completed.
- 33. Prior to the resumption of inspection services, respondents shall name in writing, with the concurrence of the Director, EED, the individual(s) responsible for performing the audits. Said auditors must have completed a course of instruction in the application of HACCP, in accordance with 9 C.F.R. § 417.7, and provide a copy of such certification to the Director, EED, prior to the resumption of inspection operations. Respondents may name a new independent third party, at any time, with the written concurrence of the Director, EED.

Recordkeeping

- 34. Respondents shall maintain full, complete and accurate written records of (a) all records required to be maintained by the FMIA and the regulations (b) all records required to be maintained under applicable Federal, State and local statutes; and (c) all SPS, SSOP, HACCP, SRM's, sampling or testing of products and other systems, plans and records required by the FMIA, the regulations or this Order.
- 35. Respondents shall notify the FSIS District Manager and/or designee of any changes or modifications to its SSOP, HACCP or other systems, programs or plans, and all associated recordkeeping forms as required by the regulations or this Order.

General Provisions

- 36. Respondents shall submit a revised "Application for Federal Meat, Poultry or Import Inspection", reflecting the management changes outlined in the Order.
- 37. Respondents or any of its owners, officers, partners, employees, agents, affiliates, or assigns shall not:

- (a) violate any section of the FMIA, State or local statutes involving the preparation, sale, transportation or attempted distribution of any adulterated or misbranded meat or poultry products;
- (b) willfully make, or cause to be made, any false entry in any account, record, or memorandum kept by respondents in compliance with applicable federal or state statutes or regulations; or willfully neglect or fail or cause to make full, true and correct entries in such accounts, records or memoranda; or fail to keep such accounts, records or memoranda that fully and correctly disclose all transactions in respondents' business;
- (c) conduct any operation requiring Federal inspection outside the official hours of operation without first submitting a written request to, and receiving written approval from FSIS officials;
- (d) commit any felony or fraudulent criminal act that results in a conviction; or assault, intimidate, or interfere or threaten to assault, intimidate, or interfere with any program employee in the performance of his or her official duties under the FMIA; and
- (e) knowingly hire or add any new individual who has been convicted, in any Federal or State court, of any felony, or more than one misdemeanor based upon the acquiring, handling, or distributing of unwholesome, mislabeled or deceptively packaged food, or fraud in connection with transaction in food; and shall immediately terminate its connection with any such individual when that individual's conviction becomes known to respondent.

Enforcement Provisions

38. The Administrator, FSIS, shall have the right to summarily withdraw inspection services upon a determination by the Director EED, or his or her designee, that one or more

conditions set forth in paragraphs 1 through 37 of this Order have been violated. It is acknowledged that respondents retain the right to request an expedited hearing pursuant to the rules of practice concerning any violation alleged as the basis for a summary withdrawal of inspection services. Nothing contained in these provisions prevents the right of respondents to appeal the decision of an FSIS employee to his/her immediate supervisor pursuant to 9 C.F.R. Part 306.5.

- 39. The provisions of this Order shall be applicable to any processing or other operations conducted under the Poultry Products Inspection Act (21 U.S.C. § 451 et. seq.), as appropriate.
- 40. Nothing in this Order shall preclude (a) any future criminal, civil, regulatory or administrative action authorized by law, regulation or otherwise, including, but not limited to any action under the FSIS rules of practice (9 C.F.R. Part 500) or (b) the referral of any matter to any agency for possible criminal, civil, or administrative proceedings.

If any provision of this Consent Decision and Order is declared invalid, such declaration shall not affect the validity of any other provision herein. The provisions of this Order shall be applicable for a period of three (3) years from the effective date of this Order.

This Order shall become effective upon issuance by the Administrative Law Judge.

STAGNO'S MEAT COMPANY Respondent Corporation RICHARD A. STAGNO President / RICHARD A. STAGNO

Respondent

BRIAN R. STACHO Respondent

SCOTT C. SAFIAN Director, Evaluation & Enforcement Division Food Safety and Inspection Service U.S. Department of Agriculture

TRACEY/MANOFF Attorney for Complainant U.S. Department of Agriculture Office of the General Counsel

ROBERT HIBBERT Attorney for Respondents

CRACE HSIEH Attorney for Respondents

> Issued this 6th day of Norman 2007 at Washington, D.C. Administrative Law Judge